REMARKS

Claims 6–9, 23 and 25–31 are pending in this application. Claims 6-9 and 26-27 are amended herein to point out particular features of the claimed invention so as to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000). These amendments are merely cosmetic and do not narrow the scope of the claimed invention. New claims 32-34 are added herein. Support for these amendments and new claims is found in the language of the original claims and throughout the specification, as set forth below. These amendments and new claims have been included to put this application in better condition for allowance and introduce no new matter, and Applicants respectfully request entry thereof. In light of these amendments and new claims and the following remarks, applicants respectfully request reconsideration of this application and allowance of the claims to issue.

Rejection under 35 U.S.C. § 112, first paragraph

The Office Action states that claims 6-9, 23 and 25-31 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action states that the claims involve an isolated nucleic acid that shares a single nucleotide in common with SEQ ID NO:1 or SEQ ID NO:3 (denoted by the phrase "a subsequence thereof"), wherein the nucleic acid would encode any polypeptide that is immunoreactive with any antibodies to EBV. The Examiner then cites Middeldorp as stating that immunoblot studies reveal an enormous diversity in EBV-specific polypeptides recognized by different patient. On this basis, the Examiner alleges that, in view of such diversity, the claims embrace a genus that encompasses polypeptides that are reactive with non-specific antibodies to EBV.

The Office Action further states that with regard to an isolated nucleic acid sequence encoding any peptide that is immunochemically reactive with antibodies to EBV, comprising at least a single residue in common with VCA-p18 or VCA-p40, such nucleic acids would also not be adequately described in the specification. The Examiner goes on to state that the specification allegedly lacks absolute description of "a functional variant of said peptide" because no function has been attributed to the claimed peptide other than being reactive with

any EBV antibody. The Examiner then states that amending the claims to recite a nucleic acid consisting of SEQ ID NO:1 or 3 would overcome this rejection.

Claim 6 is amended herein to recite an isolated nucleic acid sequence encoding: (a) a peptide immunochemically reactive with antibodies to the Epstein Barr Virus (EBV) VCA-p18 or VCA-p40 proteins, comprising an immunoreactive fragment of the VCA-p18 or VCA-p40 protein, encoded within the EBV open reading frames BFRF3 and BdRF1, respectively, or (b) a functional variant of said peptide described in (a), wherein said variant is immunochemically reactive with antibodies to the Epstein Barr Virus (EBV) VCA-p18 or VCA-p40 proteins. Claims 6 does not recite SEQ ID NO:1 or SEQ ID NO:3 or a subsequence thereof and therefore claim 6 cannot be interpreted to involve nucleic acids that share a single nucleotide in common with SEQ ID NO:1 or SEQ ID NO:3.

Furthermore, claim 6 as presented herein defines a genus of nucleic acids that encode peptides comprising an immunoreactive fragment of the VCA-p18 or VCA-p40 protein of EBV or functional variants thereof, all of which are immunoreactive with antibodies specific to VCA-p18 or VCA-p40 proteins. Thus, claim 6 is not directed to a nucleic acid that encodes any polypeptide that is reactive with any antibodies to EBV. It would be readily recognized by one of skill in the art that applicants were in possession of the genus of nucleic acids of claim 6 at the time the application was filed because the specification provides several examples of peptides of this invention (e.g., SEQ ID NOs: 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22; see pages 7-13 for description of peptides and fragments of this invention and Example 4 and Table 1) that are reactive with the EBV VCA-p18 or VCA-p40 proteins of this invention and also provides examples of nucleic acid encoding such peptides (e.g., SEQ ID NO:1, SEQ ID NO:3). In addition, claim 6 is amended herein to recite that the functional variant is immunochemically reactive with antibodies to EBV VCA-p18 or VCA-p40 proteins, as described in the specification on page 8 and thus, such variants are not reactive with any EBV antibody.

Claims 7 and 8 are amended herein to respectively recite an isolated nucleic acid sequence, comprising the nucleic acid sequence as shown in SEQ ID NO: 1 or a subsequence

thereof, wherein said subsequence encodes an Epstein-Barr Virus peptide comprising an epitope that is immunochemically reactive with antibodies to the Epstein-Barr Virus VCA-p18 protein and an isolated nucleic acid sequence, comprising the nucleic acid sequence as shown in SEQ ID NO: 3 or a subsequence thereof, wherein said subsequence encodes an Epstein-Barr Virus peptide comprising an epitope that is immunochemically reactive with antibodies to the Epstein-Barr Virus VCA-p40 protein. Thus, these claims as presented herein describe the specific antibodies with which the recited peptides of each claim are reactive and are clear in their scope, encompassing a genus of nucleic acid sequences comprising the nucleotide sequence or a subsequence of SEQ ID NO:1, wherein the subsequence encodes a peptide that comprises an epitope that is immunochemically reactive with antibodies to EBV VCA-p19 protein (claim 7) and a genus of nucleic acid sequences comprising the nucleotide sequence or a subsequence of SEQ ID NO:3, wherein the subsequence encodes a peptide that comprises an epitope that is immunochemically reactive with antibodies to EBV VCA-p40 protein (claim 8).

In both claims 7 and 8, the subsequence is defined as encoding a peptide comprising an immunoreactive epitope and thus cannot be interpreted to involve a nucleic acid that shares a single nucleotide in common with SEQ ID NO:1 or SEQ ID NO:3. It would be readily recognized by one of skill in the art that applicants were in possession of the genus of nucleic acids of claims 7 and 8 at the time the application was filed because the specification provides several examples of peptides of this invention (e.g., SEQ ID NOs: 2, 4, 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21 and 22; see pages 7-13 for description of peptides and fragments of this invention and Example 4 and Table 1) that are reactive with the EBV VCA-p18 or VCA-p40 proteins of this invention and also provides examples of nucleic acid encoding such peptides (e.g., SEQ ID NO:1, SEQ ID NO:3). The language of the claims as presented herein is consistent with the scope of the claims directed to peptides of this invention, as allowed in U.S. Patent No. 5, 424, 298, from which the present application claims priority. In particular, it is clear that applicants provide adequate support with numerous specific examples, in accordance with the written description guidelines, for a genus of nucleic acids that is not so narrowly described as to be limited to the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3 and thus do not agree with the Examiner's

suggestion to amend the claims to be drawn to a nucleic acid consisting of SEQ ID NO:1 or SEQ ID NO:3.

In view of the foregoing, it is respectfully submitted that the outstanding rejection has been overcome and applicants respectfully request its withdrawal.

Rejection under 35 U.S.C. § 102(b)

The Office Action states that claims 6-9, 23, 24 and 25-29 are rejected for allegedly being anticipated by Ambinder et al. (1989). In particular, the Office Action maintains that the claims can be construed as being drawn to a nucleic acid encoding a peptide comprising at least part of the VCA-p18 or VCA-p40 protein, wherein the peptide is reactive with antibodies to EBV, or a functional variant of the peptide. The Examiner states that the phrase "at least part of" is given the broadest reasonable interpretation as encompassing a single amino acid residue.

The Office Action then describes Ambinder et al. as disclosing a method of detecting EBV sequences in a clinical specimen by amplification involving primers and a plasmid containing EBV, which evidences the presence of a nucleic acid encoding EBV with at least one common residue with VCA-p18 or VCA-p40.

It is then stated in the Office Action that the phrase "at least part" in claim 6 is broadly interpreted to encompass a single amino acid residue. The Examiner further states that claims 7 and 8 are interpreted as being drawn to a nucleic acid comprising the nucleic acid of SEQ ID NO:1 (or SEQ ID NO:3) or a subsequence thereof, wherein the subsequence encodes an EBV peptide that is reactive with EBV antibodies. The Examiner interprets this latter phrase as encompassing any nucleic acid encoding an EBV peptide, which shares at least a single nucleotide sequence with that of SEQ ID NO:1 or 3 would meet the claim limitations and that Ambinder et al. discloses a plasmid which would have at least one nucleotide in common with SEQ ID NO:1 or SEQ ID NO:3.

As noted above, claim 6 is amended herein to delete the phrase "at least part" and is further amended to recite a nucleic acid encoding a peptide that specifically comprises an immunoreactive fragment of the VCA-p18 or VCA-p40 protein, or a functional variant thereof, which is immunoreactive with antibodies to VCA-p18 or VCA-p40. Thus, claim 6 as presented herein cannot be interpreted to encompass a single amino acid residue.

Claims 7 and 8 are amended herein to specifically recite a subsequence of a nucleic acid of SEQ ID NO:1 or SEQ ID NO:3, wherein the subsequence specifically encodes an EBV peptide comprising an epitope that is immunochemically reactive with antibodies to the VCA-p18 or VCA-p40 protein, respectively. Thus, claims 7 and 8 as presented herein cannot be interpreted to encompass a nucleic acid that shares at least a single nucleotide sequence with that of SEQ ID NO:1 or SEQ ID NO:3.

Ambinder et al. does not teach or suggest a nucleic acid meeting all of the requirements as set forth in claims 6, 7 or 8 and therefore, Ambinder et al. does not anticipate this claim. For these reasons, applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 103

The Office Action states that claims 30 and 31 are rejected under 35 U.S.C. § 103 as allegedly obvious in view of Ambinder et al. Specifically, the Office Action states that although Ambinder et al. does not teach that the primers and reagents employed in their amplification reaction should be packaged into a kit, it would have been prima facie obvious to one of ordinary skill in the art to do so in view of the conventionality of kits in the analytical arts.

As set forth above, Ambinder et al. does not teach or suggest the nucleic acids of claims 6, 7 or 8. Therefore, it cannot have been obvious at the time this invention was made from the teachings of Ambinder et al. to produce the kit of claims 30 or 31. Therefore, applicants believe this rejection has been overcome and respectfully request its withdrawal.

New claims 32-34

New claims 32-34 are presented herein that recite 1) an isolated nucleic acid sequence, comprising the nucleic acid sequence as shown in SEQ ID NO:1 or a subsequence thereof, wherein said subsequence encodes a peptide comprising at least 12 contiguous amino acids of an Epstein-Barr Virus VCA-p18 protein and wherein said peptide comprises an epitope that is immunochemically reactive with antibodies to the Epstein-Barr Virus VCA-p18 protein (claim 32), 2) an isolated nucleic acid sequence, comprising the nucleic acid sequence as shown in SEQ ID NO: 3 or a subsequence thereof, wherein said subsequence encodes a peptide comprising at least 12 contiguous amino acids of an Epstein-Barr Virus VCA-p40 protein and wherein said peptide comprises an epitope that is immunochemically reactive with antibodies to the Epstein-Barr Virus VCA-p40 protein (claim 33), and 3) an isolated nucleic acid sequence, comprising the nucleic acid sequence as shown in SEQ ID NO:1 or a subsequence thereof, wherein said subsequence encodes an Epstein-Barr Virus peptide comprising the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:6 or a combination of both, wherein said peptide is immunochemically reactive with antibodies to the Epstein-Barr Virus VCA-p18 protein (claim 34).

Support for these new claims can be found throughout the specification and in particular at least in Examples 4 and 5 and Figures 4-6, wherein studies are described in which applicants produced a large number of peptides "...with a length of 12 amino acids (AA) and an overlap of 11 AA of the AA sequence of ORF BFRF3 and BdRF1"(page 30, bottom paragraph) and screened each peptide for immunoreactivity with EBV specific antibodies. Thus, the specification provides adequate written support and enablement for the genus of nucleic acids encoding 12mer peptides as set forth in new claims 32-34. These nucleic acids encoding these 12mer peptides are free of the cited art, as such nucleic acids are neither taught nor suggested by Ambinder et al. Therefore, applicants respectfully request entry and allowance of these new claims.

The points and concerns raised in the outstanding Office Action having been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is respectfully requested. Should the Examiner have any remaining

concerns, the Examiner is invited and encouraged to contact the undersigned attorney in order to expedite the prosecution of this application.

No fee is believed due with this response. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

Mary L. Miller
Registration No. 39,303

Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

CERTIFICATE OF EXPRESS MAILING

"Express Mail" mailing label number: EV 674759364 US Date of Deposit: March 24, 2005
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cathy Schetzina